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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:	)	Group Art Unit: 1631
McDONOUGH *et al.*	)	Examiner: Marschel, A.
Serial No. 08/480,472	)	Atty. Docket No. GP034-03.DV1
Filed: June 6, 1995	)	**VIA FACSIMILE**
For: NUCLEIC ACID SEQUENCE AMPLIFICATION	)	

DECLARATION UNDER 37 C.F.R. § 1.132

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

I, Yeasing Y. Yang, am a co-inventor of the above-identified patent application and, upon information and belief, hereby declare as follows:

1. I performed an experiment designed to compare the relative effectiveness of different primer sets to amplify *M. tuberculosis* rRNA in a transcription-based amplification reaction. The methods and results of this experiment are recorded at page 94 (front and back) of Gen-Probe lab notebook number 2120, which had been issued to me. *See* Exhibit A. For this experiment, I compared a first primer set targeting a 23S rRNA region of *M. tuberculosis* with three other primer sets, each targeting a similar 16S rRNA region of *M. tuberculosis*. The primer set targeting *M. tuberculosis* 23S rRNA included a promoter-primer identified as T7AMtbB(-)290-3'RP and a primer identified as Mtb(+)237, and the primer sets targeting *M. tuberculosis* 16S rRNA each included a primer identified as MgoA(+)146 in combination with a promoter-primer identified as T7AMtbA (-)246, T7AMtbA(-)247 or T7AMtbA(-)251. Prior to this experiment, the first primer set had been considered for commercial development by Gen-Probe, the inventors' employer and assignee of the subject application. The primer sets of this experiment were all tested under identical conditions.

2. The primer set which included the promoter-primer identified as T7AMtbA (-)246 and the primer identified as Mtb(+)146 corresponds to SEQ ID NO:22 (with the optional promoter-sequence) and SEQ ID NO:2, respectively, of the subject application. This can be confirmed from the entries in my notebook, where it is indicated that information regarding the preparation of these sequences can be found at page 71 of Gen-Probe lab notebook number 1802, which issued to Liz Bescher of Gen-Probe's oligonucleotide synthesis group, and page 62 of Gen-Probe lab notebook number 2082, which issued to Lisa Fukunaga of Gen-Probe's oligonucleotide synthesis group. *See* Exhibit A. Page 62 of lab notebook number 2082 records the purification of MgoA146(+) and indicates that synthesis information for this sequence can be found on page 60 of Gen-Probe lab notebook number 1854, which issued to Sheryl Roberts of Gen-Probe's oligonucleotide synthesis group. *See* Exhibit B. The synthesis and purification information recorded on page 60 of lab notebook number 1854 identifies MgoA146(+) by base sequence. *See* Exhibit C. Page 71 of lab notebook number 1802, which issued to Liz Bescher, records the purification of T7AMtbA(-)246 and indicates that synthesis information for this sequence can be found on page 20 of Gen-Probe lab notebook number 1746, which also issued to Liz Bescher. Exhibit D. The synthesis information on page 20 of lab notebook number 1746 identifies T7AMtbA(-)246 by base sequence. *See* Exhibit E.

3. The experimental results are recorded in relative light units (RLU), a measure of chemiluminescence, on page 94 of lab notebook number 2120. *See* Exhibit A. The first set of samples 1-6 recorded in the results provide amplification data for the first primer set, and samples 3-8, recorded below negative control samples 1 and 2, provide amplification data for the T7AMtbA (-)246/MgoA146(+) primer set. These results unexpectedly demonstrated that the primer set made up of T7AMtbA(-)246 and MgoA146(+) exhibited substantially less variability that the first primer set.

DECLARATION

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I hereby declare that all statements made herein of my own knowledge are true, and that statements made on information and belief are believed to be true; and further, that these statements are made with the knowledge that willful false statements, and the like so made, are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statement may jeopardize the validity of this application and any patent issuing therefrom.

Date: 11-5-04 By: Yeasing Yang

Yeasing Y. Yang